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# **EPA's Ecological Risk Assessment Initiative:**

Progress Report of the Ecological Committee on FIFRA Risk Assessment Methods: 1. Workgroup Formation and Process.

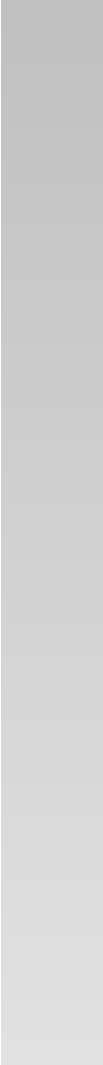


I. M. Sunzenauer, and D.S. Spatz,  
Office of Pesticide Programs, U.S. Environmental  
Protection Agency, Washington, DC 20460; and  
D. Fischer, Agriculture Division, Bayer Corporation,  
Stilwell, KS 66085



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**May 1996**

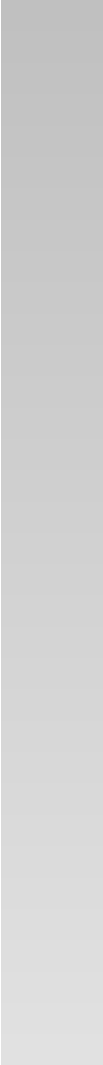


The Environmental Fate and Effects Division within the Office of Pesticide Programs presented their Ecological Risk Assessment Methodology to the FIFRA Scientific Advisory Panel (SAP).



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## **SAP Recommendations**

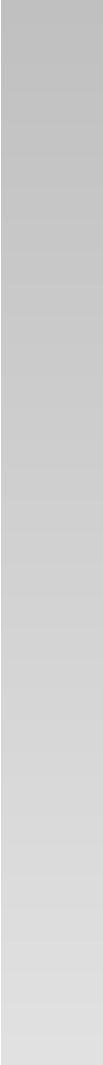


While recognizing and generally reaffirming the utility of OPP's current ecological risk assessments, the Panel indicated that OPP, due to data gaps, is "trapped" in single point deterministic risk assessments and should move toward probabilistic types of assessments that address the magnitude, uncertainty and variation involved in the provided estimates.



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# EFED Response to the SAP

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- Commitment to design a process for developing and validating probabilistic assessment tools and methodologies.
  - Methods developed will reflect a solid foundation in environmental toxicology and environmental fate, including the transport, degradation, and accumulation of pesticides in the environment.
  - Commitment to involve stakeholders- outreach.



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# **December 1996**



## **Formation of the Workshop Organizing Committee (WOK)**

Edward Fite, EPA

Paul Mastradone, EPA

Ron Parker, EPA

Dana Spatz, EPA

Ann Stavola, EPA

Ingrid Sunzenauer, EPA

Jim Wolf, EPA

Dave Fischer, Bayer Corp.

Jim Gagne, Am. Cyanamid

Dennis Laskowski, Dow Elanco

Ray McAllister, ACPA

Kevin Reinert, Rohm and Haas

Rick Stanton, Valent USA



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# Responsibilities and Accomplishments of the WOK

- Outreach-
  - Pesticide Program Dialog Committee (PPDC)
  - State FIFRA Issues Research and Evaluation Group (SFIREG)
  - Professional Meetings (ACS, SETAC, SRA)
- Invited participants to ECOFRAM- aquatic and terrestrial workgroups.
- Held June 23, 1997 open workshop. "Evaluating Ecological Risk: Developing FIFRA Probabilistic Tools and Processes."
- Two additional workshops are planned. Summer 1998- workgroups will share results and obtain peer review. Fall 1998- open meeting for ECOFRAM to share final results and recommendations.



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**June 1997**

**Formation of the Ecological Committee  
On FIFRA Risk Assessment Methods  
(ECOFRAM)**

- Responsible for conducting the primary review of the current assessment process and developing new tools and methodologies.
- Identify additional methods, development and validation needs to ensure that the assessment process supports environmental decisions that are scientifically defensible.





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# 1001 Risk Manager Questions

- What is the magnitude and probability of these effects?
- What are the effects of concern?
- Why are they of concern?
- Will there be population(s) impacts?
- Will the population(s) recover?
- Are the effects seen across different species?
- Will the effects influence density and diversity?
- How confident are we in our estimate of the effects?
- What models did we use? Have they been validated? Are they widely accepted and scientifically sound?
- Is there any monitoring data? Which data are more reliable, lab or monitoring? How have you factored the monitoring data into your assessment?



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# Charge to the Terrestrial and Aquatic Workgroups

- Develop processes and tools for predicting the magnitude and probabilities of adverse effects to non-target aquatic and terrestrial species resulting from the use of pesticides.
- Standardized procedures that integrate estimates of pesticide exposure with knowledge about potential adverse effects. Account for biological factors such as species sensitivity, habitat, dietary/behavior mechanisms. Account for environmental factors such as transport, accumulation, fate, climate, application techniques, and formulation.
- Address uncertainty in a quantitative manner and recommend procedures to appropriately validate tools and assumptions.
- Keep within the context of the FIFRA regulatory perspective and follow the outline provided by EPA's Framework for Ecological Risk Assessment (U.S. EPA/ORD, 1992).



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# Workgroup Members: Aquatic

## Exposure

Paul Hendley (Chair)- Zeneca  
James Baker- Iowa State Univ.  
Lawrence Burns- ORD/EPA  
David Farrar- OPP/EPA  
Alan Hosmer- Novartis  
R. David Jones- OPP/EPA  
Walton Low- USGS  
Mark Russell- Du Pont  
Mari Stavanja- FL Bureau of Pesticide  
W. Martin Williams- Waterborne Env.  
James Wolf- OPP/EPA

## Effects

Jeff Giddings (Chair)- Springborn  
Larry Barnthouse- McLaren-Hart  
Jerry Clark- Natl. Fish & Wildlife Fou.  
A. Tilghman Hall- Bayer  
Michael McKee- Monsanto  
Michael Newman- Univ. of Georgia  
Kevin Reinert- Rohm and Haas  
Robert Sebastien- Health Canada  
Ann Stavola- OPP/EPA  
Keith Solomon- Univ. of Guelph  
Les Touart- OPP/EPA  
Randy Wentsel- U.S. Army



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# Workgroup Members: Terrestrial

## Exposure

Edward Fite (Chair)- OPP/EPA  
Larry Brewer- Ecotox. & Biosystems  
Kristin Brugger- Du Pont  
David Fischer- Bayer  
Andy Hart- UK MAFF  
Dennis Laskowski- DowElanco  
Paul Mastradone- OPP/EPA  
Robert Menzer- ORD/EPA  
Daryl Morehead- Texas Tech Univ.  
Henry Nelson- OPP/EPA  
Raymond O'Connor- Univ. of Maine  
Ron Parker- OPP/EPA  
Duane Wolf- Univ. of Arkansas

## Effects

Michael Willig (Chair)- Texas Tech  
Alain Baril- Environment Canada  
Richard Bennett- Eco. Planning & Tox  
John Eisemann- OPP/EPA  
William Erickson- OPP/EPA  
Susan Ferenc- USDA  
Michael Fry- National Audubon Soc.  
James Gagne- American Cyanamid  
Michael Hooper- Clemson Univ.  
Thomas Lacher- Texas A&M  
Monte Mayes- Dow Chemical  
Diana Post- Rachel Carson Council  
Robert Ringer- Michigan State (Ret.)  
Jennifer Shaw- Zeneca



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**August 1997**



**Progress of ECOFRAM Workgroups**



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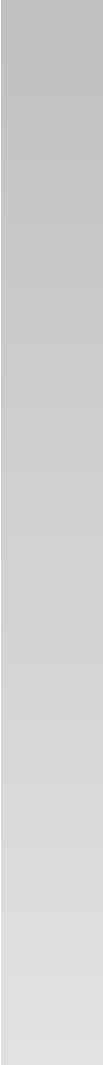
# Terrestrial Workgroup Approach

- Define assessment questions (probability and magnitude of effects).
- Develop conceptual model (exposure and effects).
- Identify major variables that influence effects to nontarget species.
- Define distribution for these variables or how to estimate them.
- Construct models and perform sensitivity analysis.
- Identify data needed to support models.
- Develop risk assessment process incorporating the models.
- Define additional developmental work and validation requirements.



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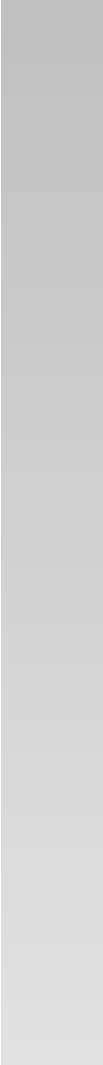
# Aquatic Workgroup Approach

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- Time-to-event analysis
  - Pulsed exposures
  - Life table and population models
  - Intraspecific variability in sensitivity
  - Interspecific variability in sensitivity
  - Sensitivity distribution subsets, resampling
  - Ecosystem models
  - Mesocosms
  - Behavioral effects
  - Sediment toxicity/Equilibrium partitioning



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# Milestones

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|--|------------------|
| ✓ Formation of WOK   | December 1996    |
| ✓ Formation of ECOFRAM and<br>Initial Outreach Workshop                | June 1997        |
| ✓ Consultation with SAP  | September 1997   |
| ✓ Presentation of Interim Progress at<br>Professional Society Meetings | Fall/Winter 1997 |
| ▶ ECOFRAM Reports  | Spring 1998      |
| ▶ Peer Review Workshop   | Fall 1998        |
| ▶ SAP Review of Proposed Ecological<br>Risk Assessment Improvements    | Winter 1998      |
| ▶ OPP Implements Use of New Tools and Processes                        | Spring 1999      |



**[www.epa.gov/oppefed1/ecorisk/index.htm](http://www.epa.gov/oppefed1/ecorisk/index.htm)**